

## REMARKS

### I. INTRODUCTION

The Office Action mailed November 19, 2007, has been carefully considered. In light of the present amendment and the following discussion, favorable reconsideration of this application is respectfully requested.

### II. STATUS OF THE CLAIMS

Claims 39 and 43-61 are pending with Claims 39, 49, and 58 being independent. New Claims 47-61 are added herewith, Claims 40-42 are cancelled herewith, and Claims 1-38 were previously cancelled. By the present amendment, Claim 39 is amended and Claim 49 is added to recite a step of applying “electrical stimulation [that] mimics a natural functioning of the joint without producing destructive wear and tear on the joint by stimulating said at least two muscle groups in a pattern of normal joint action based on an electromyographic output,” and Claim 58 is added to recite a step of applying “electrical stimulation [that] is adapted to mimic a natural sequencing of said first and second musculature without producing destructive wear and tear on the joint based on an electromyographic output ... wherein the joint is in a non-weight bearing position.” Claims 43-46 are amended to address minor informalities. As support for the amendments and the new claims is provided, for example, at paragraph [0016] of the Specification, it is respectfully submitted that no new matter is added by this amendment.

### III. SUMMARY OF THE OFFICE ACTION

In the November 19, 2007, Office Action, the Examiner rejects Claims 39, 40, and 43 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,393,328 to *McGraw et al* (hereinafter “*McGraw*”); rejects Claims 39-42, 45, and 46 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 3,083,712 to *Keegan, Jr.* (hereinafter “*Keegan*”); rejects Claims

39-42 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,165,750 to *Aleev et al.* (hereinafter “*Aleev*”); rejects Claims 39-42 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,350,415 to *Cywinski* (hereinafter “*Cywinski*”); rejects Claim 43 under 35 U.S.C. § 103(a) as unpatentable over *Keegan* in view of Official Notice taken by the Examiner; and rejects Claims 39, 43, and 44 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,324,317 to *Reiss* (hereinafter “*Reiss*”) in view of *Keegan*. For the reasons discussed below, the rejections are respectfully traversed.

#### IV. CLAIM REJECTIONS

##### A. Rejection of Claims 39, 40, and 43 Under 35 U.S.C. § 102(e) As Anticipated By *McGraw*

The Office Action rejects Claims 39, 40, and 43 under 35 U.S.C. § 102(e) as anticipated by *McGraw*. Claim 40 is cancelled and Claim 43 depends from Claim 39. As amended, Claim 39 recites a step of applying “electrical stimulation [that] mimics a natural functioning of the joint without producing destructive wear and tear on the joint by stimulating said at least two muscle groups in a pattern of normal joint action based on an electromyographic output.” By contrast, *McGraw* relates only to applying electrical stimulation to muscle groups simultaneously or asynchronously.

More specifically, *McGraw* only describes two “modes” of electrical stimulation: a normal mode, wherein electrical stimulation is applied to muscle groups “at the same time” (col. 5, lines 49-54); and an alternate, mode wherein electrical stimulation is applied to one muscle group and not applied to other muscle groups in an alternating pattern (col. 5, lines 59-64). The pulsed muscle stimulation of *McGraw* is only described as being applied after selecting one of those two modes of stimulation (col. 20, lines 52-54). Stimulation patterns of normal joint action based on an electromyographic output, however, include periods where two muscle groups are stimulated at the same time as well as periods where one muscle group is stimulated while the other

is not, i.e., some “on” time overlap between muscle groups and some “on” time for each muscle group during the other muscle group’s “off” time. Accordingly, because the device of *McGraw* can only apply electrical stimulation to all muscle groups at the same time or apply electrical stimulation alternately between muscle groups without overlap, Applicants respectfully submit that pattern recited in Claim 39 patentably distinguishes over *McGraw*.

Likewise, it is respectfully submitted that dependent Claim 43 patentably distinguishes over *McGraw* for at least the reasons set forth with respect to Claim 39. Thus, because *McGraw* fails to disclose or suggest all of the features of Claims 39 and 43, Applicants respectfully request reconsideration and withdrawal of the rejection of those claims under 35 U.S.C. § 102(e).

**B. The Rejection of Claims 39-42, 45, and 46 Under 35 U.S.C. § 102(b) As Anticipated By Keegan**

The Office Action rejects Claims 39-42, 45, and 46 under 35 U.S.C. § 102(b) as anticipated by *Keegan*. Claims 40-42 are cancelled, and Claims 45 and 46 depend from Claim 39. As amended, Claim 39 recites electrical stimulation that “mimics a natural functioning of the joint without producing destructive wear and tear on the joint.” By contrast, *Keegan* relates only to applying electrical stimulation to cause actual functioning of a joint.

More specifically, the device of *Keegan* is directed to synthetically stimulating muscles of patients with paralysis to cause a joint to “provide a natural function” (col. 1, lines 49-53). Such stimulation does not mimic natural functioning of a joint, but rather causes actual functioning of the joint. For example, the electrical stimulation of *Keegan* “causes muscle contraction producing toe elevation, dorsiflexion, and a turning of the foot, eversion” (col. 3, lines 41-43). Such stimulation not only causes actual joint functioning, but the resulting joint functioning also causes destructive wear and tear on the joint. Moreover, the device of *Keegan*

only utilizes two electrodes 13 and 17 to provide electrical stimulation, while the method recited in Claim 39 requires the use of at least two first electrodes and at least two second electrodes to provide electrical stimulation. Accordingly, Applicants respectfully submit that Claim 39 patentably distinguishes over *Keegan*.

Likewise, it is respectfully submitted that dependent Claims 45 and 46 patentably distinguish over *Keegan* for at least the reasons set forth with respect to Claim 39. Thus, because *Keegan* fails to disclose or suggest all of the features of Claims 39, 45, and 46, Applicants respectfully request reconsideration and withdrawal of the rejection of those claims under 35 U.S.C. § 102(b).

C. **The Rejection of Claims 39-42 Under 35 U.S.C. § 102(b) As Anticipated By *Aleev***

The Office Action rejects Claims 39-42 under 35 U.S.C. § 102(b) as anticipated by *Aleev*. Claims 40-42 are cancelled. As amended Claim 39 recites electrical stimulation that “mimics a natural functioning of the joint without producing destructive wear and tear on the joint.” By contrast, *Aleev*, like *Keegan*, relates only to applying electrical stimulation to cause actual functioning of a joint.

More specifically, the device of *Aleev* is directed to “improv[ing] the correspondence between actually performed and programmed movements” (col. 4, lines 49-53). The device of *Aleev* senses the bioelectric activity in the muscles of a first person who sets the programmed movements and applies that program to a second person whose muscles actually perform the programmed movement (col. 17, lines 8-14). Such stimulation not only causes actual joint functioning rather than mimicking joint functioning, but the resulting joint functioning also causes destructive wear and tear on the joint. Moreover, the device of *Aleev* is directed to restoring lost motor skills (col. 1, lines 22-28), not “decreasing degenerative processes in a joint”

as recited in amended Claim 39. Accordingly, Applicants respectfully submit that Claim 39 patentably distinguishes over *Aleev*.

Thus, because *Aleev* fails to disclose or suggest all of the features of Claim 39, Applicants respectfully request reconsideration and withdrawal of the rejection of that claim under 35 U.S.C. § 102(b).

**D. The Rejection of Claims 39-42 Under 35 U.S.C. § 102(b) As Anticipated By *Cywinski***

The Office Action rejects Claims 39-42 under 35 U.S.C. § 102(b) as anticipated by *Cywinski*. Claims 40-42 are cancelled. As amended Claim 39 recites electrical stimulation that “mimics a natural functioning of the joint without producing destructive wear and tear on the joint by stimulating said at least two muscle groups in a pattern of normal joint action.” By contrast, *Cywinski* relates only to applying electrical stimulation at a level below that required to mimic a natural functioning of the joint and applying electrical stimulation only to a single muscle group.

More specifically, *Cywinski* relates to a device for applying trophic neuromuscular electrical stimulation to muscles, patterned after motor unit action potentials (MUAPs) (col. 3, lines 35-41). MUAPS are discharges in individual groups of muscle cells that contract together (col. 2, lines 30-33). The electrical stimulation described in *Cywinski*, however, is applied at a level below that required to cause fused and forceful contractions of the stimulated muscles (col. 2, lines 33-36). Accordingly, the device of *Cywinski* cannot “mimic[] a natural functioning of the joint” as recited in Claim 39. Moreover, the “patterned” stimulation described in *Cywinski* is applied only to a single muscle group via two electrodes and, therefore, cannot “stimulat[e] said at least two muscle groups in a pattern of normal joint action.” Accordingly, Applicants respectfully submit that Claim 39 patentably distinguishes over *Cywinski*.

Thus, because *Cywinski* fails to disclose or suggest all of the features of Claim 39, Applicants respectfully request reconsideration and withdrawal of the rejection of that claim under 35 U.S.C. § 102(b).

**E. The Rejection of Claim 43 under 35 U.S.C. § 103(a) As Unpatentable Over Keegan In View of Official Notice Taken By the Examiner**

The Office Action rejects Claim 43 under 35 U.S.C. § 103(a) as unpatentable over *Keegan* in view of Official Notice taken by the Examiner. Claim 43 depends from Claim 39. As discussed above, *Keegan* fails to disclose or suggest all of the recited features of Claim 39. Accordingly, Applicants respectfully submit that the outstanding Office Action has failed to provide a *prima facie* case of obviousness of Claim 43, and it is therefore respectfully requested that the rejection of that claim under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

**F. The Rejection of Claims 39, 43, and 44 Under 35 U.S.C. § 103(a) As Unpatentable Over Reiss in view of Keegan**

The Office Action rejects Claims 39, 43, and 44 under 35 U.S.C. § 103(a) as unpatentable over *Reiss* in view of *Keegan*. Claims 43 and 44 depend from Claim 39. As the Office Action acknowledges, *Reiss* fails to disclose a mode of operation in which the electrical stimulation is applied in the pattern of Claim 39. And, as discussed above, *Keegan* fails to disclose or suggest the stimulation pattern of Claim 39. Accordingly, *Keegan* fails to cure the deficiencies of *Reiss*. Applicants therefore respectfully submit that the outstanding Office Action has failed to provide a *prima facie* case of obviousness of Claims 39, 43, and 44, and it is respectfully requested that the rejection of those claims under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

## **V. NEW CLAIMS**

New Claims 47-61 are also believed to patentably distinguish over the references of record, as those claims recite features not disclosed or suggested in those references. More specifically, as discussed above, Claims 48-62 each recite electrical stimulation that mimics the natural functioning of a joint without causing wear and tear based on an electromyographic pattern, which is not disclosed or suggested by any of the cited references. In addition, each of new independent Claims 49 and 58 also recites additional features not found in the cited references.

For example, Claim 49 recites an additional step of applying electrical stimulation that “bathes the affected body segment with interferential stimulation.” And, Claim 58 recites that the electrical stimulation is applied while “the joint is in a non-weight bearing position.” Nowhere do the cited references disclose or suggest applying electrical stimulation that mimics the natural functioning of a joint without causing wear and tear based on an electromyographic pattern either with a second step of stimulation that is interferential stimulation or while the joint is in a non-weight bearing position. Moreover, Claim 58-61 are directed to a “method for improvement of synovial fluid in a joint in a patient having a degenerative joint disease.” None of the cited references disclose or suggest that form of treatment. Accordingly, none of the cited references disclose or suggest the features recited in new Claims 47-61, and Applicants respectfully submit that Claims 47-61 are in condition for allowance.

## **VI. CONCLUSION**

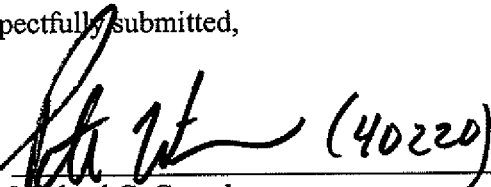
Consequently, in view of the foregoing discussion and present amendments, it is respectfully submitted that this application is in condition for allowance. An early and favorable action is therefore respectfully requested.

Please charge any shortage of fees or credit any overpayment thereof to BLANK ROME LLP, Deposit Account No. 23-2185 (000309-00049). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this report, Applicant hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized above.

Respectfully submitted,

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